

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

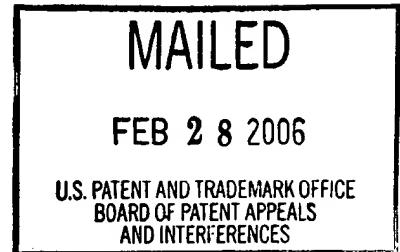
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte H. PAUL REDMOND and ROLF W. PFIRRMANN

Appeal No. 2005-2671
Application No. 09/971,774

HEARD: January 12, 2006



Before SCHEINER, MILLS, and GRIMES, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 1-12 and 26, which are all of the claims pending in this application.

Claims 1-4, 6, 9, 10 and 26 are illustrative of the claims on appeal and read as follows:

1. A method of treating abdominal cancer comprising performing a surgery on a patient's abdomen by forming a surgical opening in said patient's abdomen, surgically removing a cancerous tumor from the patient's abdomen through the surgical opening, and closing said surgical opening, the method including a step of administering taurolidine, taurultam or a mixture thereof to the patient's abdomen prior to said closing of said surgical opening and after said surgically removing said cancerous tumor, so as to treat cancer in the patient's abdomen, further including a step of additionally administering taurolidine, taurultam or a mixture thereof to said patient after said closing said surgical opening.

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2. The method of claim 1 wherein, after closing said surgical opening, said taurolidine, taurultam or mixture thereof is administered to said patient by installation or intravenous infusion.
3. The method of claim 2 wherein, further including the step of additionally administering taurolidine, taurultam or a mixture thereof to said patient prior to forming said surgical opening in said patient's abdomen.
4. The method of claim 1, further including the step of additionally administering taurolidine, taurultam or a mixture thereof to said patient prior to forming said surgical opening in said patient's abdomen.
6. The method of claim 5 wherein during said surgery, said administering said taurolidine, taurultam or mixture thereof to said patient's abdomen is conducted by passing a solution containing said taurolidine, taurultam or mixture thereof through said trocar tube so as to contact internal tissue of the patient with said solution.
9. The method of claim 8 wherein said solution further contains heparin, a heparin derivative or hyaluronic acid.
10. The method of claim 6 further comprising the step of additionally introducing said solution into said patient prior to said laparoscopic tumor surgery and prior to introducing said trocar tube into said patient.
26. The method of claim 1 further comprising administering to said patient 5-fluorouracil (5-FU) at a dosage within the range of about 0.1-1000 mg.

The prior art references cited by the examiner are:

Allgood et al. (Allgood)	5,176,651	Jan. 5, 1993
Nicolson et al. (Nicolson)	5,262,403	Nov. 16, 1993
Monson	WO 92/00743	Jan. 23, 1992

Jacobi, C. A., et al. (Jacobi) "Peritoneal instillation of taurolidine and heparin for the prevention of intraperitoneal tumor growth and trocar metastases in laparoscopic operations using rats as a model" Langenbecks Arch. Chir., Vol. 382, Supp. 1, pp. 31-36 (1997). [English Translation]

Physicians' Desk Reference, Entry for 5-Fluorouracil, pp. 2034-5 (1995).

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Grounds of Rejection

I. Claims 1-5, 8, 9, 11 and 12 stand rejected under 35 U.S.C. 103(a) over Jacobi in view of Monson.

II. Claims 1-12 stand rejected under 35 U.S.C. 103(a) over Jacobi and Monson in view of Allgood.

III. Claims 1-5, 8, 9, 11 and 12 stand rejected under 35 U.S.C. 103(a) over Jacobi and Monson in view of Nicholson.

IV. Claims 1-5, 8, 9, 11, 12 and 26 stand rejected under 35 U.S.C. 103(a) over Jacobi and Monson in view of Physicians Desk Reference (PDR).

We affirm the rejections I-IV with respect to claims 1-2, 5, 6-9, 11-12 and 26. We reverse the rejections I-IV with respect to claims 3, 4 and 10.

DISCUSSION

Obviousness

I. Claims 1-5, 8, 9, 11 and 12 stand rejected under 35 U.S.C. 103(a) over Jacobi in view of Monson.

We preliminarily note that appellants have only argued claims 3 and 4 separately with respect to this rejection, thus claims 1, 2, 5, 9, 11 and 12 stand or fall together.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is

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established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). An obviousness analysis requires that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). With this as background, we analyze the prior art applied by the examiner in the rejection of the claims on appeal.

According to the Examiner (Answer, pages 3-4)

JACOBI teaches that the intraperitoneal administration [sic] of taurolidine or a combination of taurolidine and heparin at the time of laparoscopic surgery for tumor removal reduces the incidence of tumor growth and trocar metastases. See abstract. The reference discloses that lavage with taurolidine and heparin is performed in human patients undergoing laparoscopic resection of malignancies. See last paragraph of the reference on page S35. The reference does not explicitly describe each and every step in such a procedure.

The reference does not teach the use of taurultam in the concentration range recited in this procedure or the use [of] such a solution before surgery or after closing - step (5).

To make up for the failure of Jacobi to teach administration of taurolidine after surgical closing, the examiner relies on Monson. According to the examiner, the reference states "[i]t is particularly beneficial to use taurolidine and/or taurultam [to] prevent the spread of metastases, especially following surgical removal of tumours." Answer, page 4.

The examiner concludes (Answer, page 5)

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[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to administer a solution of taurolidine and/or taurultam (with or without heparin) during laparoscopic abdominal cancer surgery. MONSON had taught that these species (taurolidine and/or taurultam) are functional equivalents for the inhibition of metastases. ... It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer a solution of taurolidine and/or taurultam before and/or after cancer surgery for the benefits of treating malignancies as well as prevention of metastases, taught by MONSON. ...

We agree that the examiner has established a prima facie case of obviousness with respect to claim 1. Jacobi teaches administration of taurolidine during surgery in the form of a postoperative lavage. Translation, page 9. Thus, Jacobi teaches the step of "the method including a step of administering taurolidine, taurultam or a mixture thereof to the patient's abdomen prior to said closing of said surgical opening and after said surgically removing said cancerous tumor" as claimed. Monson clearly suggests the use of taurolidine, especially following the surgical removal of tumors. Monson, page 3. Thus, in our view, the examiner has provided sufficient evidence to support a prima facie case of obviousness, including a reason suggestion or motivation to combine the cited references.

Appellants argue in response that (Brief, page 7)

There is no suggestion in the applied prior art of the specific steps of the present claims, wherein the tumor is removed, taurolidine and/or taurultam is administered to the abdomen prior to closing of the surgical opening and after surgical removal of the tumor, and additionally administering taurolidine and/or taurultam to the patient after closing the surgical opening.

With respect to claim 1, we disagree with appellants' argument. We agree with the examiner that "Appellants fail to state why the combination of references is invalid."

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Answer, page 8. On the other hand, Monson appears to reasonably provide an appropriate suggestion to one of ordinary skill in the art at the time of the present invention to administer taurolidine after closing a surgical opening and removing a tumor.

We, however, agree with appellants that claims 3 and 4 stand on a different footing than claim 1. The examiner argues in the Answer, at page 4, that "patients in need of metastasis prevention would include those scheduled for cancer surgery and those who have had cancer surgery." Appellants respond arguing "[w]ith respect to claims 3, 4 and 10, which further specify additionally administering taurolidine and/or taurultam to the patient prior to forming the surgical opening in the patient's abdomen, no combination of the cited references suggest this embodiment of the invention."

Brief, page 7.

The examiner has not indicated and we do not find a particular suggestion in Monson of administration of taurolidine or taurultam prior to conducting surgery for removal of a tumor. Therefore, we reverse the rejection of the examiner as to claims 3 and 4.

II. Claims 1-12 stand rejected under 35 U.S.C. 103(a) over Jacobi and Monson in view of Allgood.

With respect to this rejection, appellants separately argue the limitation of claim 6. Thus we address claim 6 separately, and claims 1-5 and 7-12 stand or fall together

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for purposes of this rejection.

The examiner recognizes that Jacobi and Monson "are silent regarding the administration of the taurolidine and/or taurultam solution by passing it through a trocar but does clearly suggest the use of a trocar for performing the surgical procedure." Answer, page 6. The examiner relies on Allgood for the disclosure that "laparoscopy typically comprises the use of a cannula inserted through a trocar for irrigation of the surgical site" and that "[b]y definition, irrigation comprises the administration of fluid to said site." Answer, page 6. Thus, the examiner finds that (Id.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer taurolidine and/or taurultam in the JACOBI procedure via a cannula inserted through the trocar, as JACOBI had taught that the administration of the solution is beneficial in the prevention of trocar metastases. Fluid delivery via a cannula through a trocar in laparoscopy is standard procedure, as would be [sic, have been] known to one of ordinary skill.

Appellants rely on their unsuccessful previous arguments with respect to the combination of Jacobi and Monson, to address this rejection. Appellants further argue only the limitation of claim 6, stating, that Allgood includes the description of a "sealing means in the trocar to prevent the flow of fluid." Brief, page 8. Appellants, however, fail to acknowledge the disclosure indicated by the examiner of the use of the trocar housing for the insertion of a suction/irrigation cannula. Answer, page 9. Thus, we are unpersuaded by appellants' argument and the rejection of claim 6 over Jacobi, Monson and Allgood is affirmed. We note claim 10 includes the same claim limitation as claims 3 and 4, addressed herein. Consistent with the above discussion with respect to

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claims 3 and 4, the rejection of claims 3, 4 and 10 over Jacobi, Monson and Allgood is reversed. Thus, rejection II is affirmed with respect to claims 1-2, 5-9 and 11-12.

III. Claims 1-5, 8, 9, 11 and 12 stand rejected under 35 U.S.C. 103(a) over Jacobi and Monson in view of Nicolson.

We have affirmed the rejection of claims 1, 2, 5, 8, 9, 11 and 12 over Jacobi and Monson. In this rejection the examiner relies on Nicolson to reject claim 9, drawn to the use of heparin or hyaluronic acid in combination with taurolidine and/or taurultam. The examiner notes that Jacobin and Monson teach the administration of taurolidine and/or taurultam with heparin but not hyaluronic acid. The examiner relies on the disclosure of Nicolson that "glycosaminoglycans such as heparin and hyaluronic acid are useful for the inhibition of tumor invasiveness and metastasis. See abstract and col 10, lines 4-10." Answer, page 7.

Above, we have affirmed the rejection of claim 9 over Jacobi in view of Monson. Appellants' further discussion of Nicolson does not overcome the underlying rejection of Jacobi in view of Monson. Moreover, appellants fail to provide a reason why one of ordinary skill in the art would not administer taurolidine and/or taurultam with heparin or an alternative glycosaminoglycan to heparin, i.e., hyaluronic acid, for the similar purpose of inhibiting tumor invasiveness and tumor metastasis. Therefore the rejection of claim 9 over Jacobi and Monson in view of Nicolson is affirmed. The examiner does not rely on the disclosure of Nicolson to reject claims 3 and 4. For the reasons

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indicated in the discussion of rejection I, claims 3 and 4 are not obvious in view of Jacobi and Monson. Thus rejection III is reversed with respect to claims 3 and 4.

IV. Claims 1-5, 8, 9, 11, 12 and 26 stand rejected under 35 U.S.C. 103(a) over Jacobi and Monson in view of Physicians Desk Reference (PDR).

Jacobi is discussed above. Monson additionally teaches that the administration of taurolidine and taurultam may be in combination with other anti-tumor therapeutics.

Page 3, lines 1-7. Answer, page 7.

The examiner relies on the additional reference, PDR, to meet the limitations of single dependent claim 26, directed to the method of claim 1 wherein the method further comprises administration of 5-FU (fluorouracil) at a dosage within the range of about 0.1-1000 mg. The PDR teaches that 5-FU has utility in the treatment of a variety of cancers and has a suggested dosage of about 500 mg/day.

Appellants address this argument of the examiner, taking the position that the PDR does not cure the "manifest deficiency" of the combination of Jacobi and Monson. Brief, page 11.

In view of the above, we do not find the appellants have sufficiently rebutted the prima facie case of obviousness established by the examiner with respect to claim 26. The rejection of claim 26 is affirmed. For the reasons discussed above, the rejection is also affirmed with respect to claims 1, 2, 5, 6, 7, 8, 9, 11 and 12, but reversed with respect to claims 3 and 4.

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CONCLUSION

Therefore, we affirm the rejections I-IV of claims 1, 2, 5-9, 11, 12 and 26. We reverse the rejections I-IV of claims 3, 4 and 10 for the reasons herein. No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

Toni R. Scheiner

TONI R. SCHEINER
Administrative Patent Judge

Demetra J. Mills

DEMETRA J. MILLS
Administrative Patent Judge

Eric Grimes

ERIC GRIMES
Administrative Patent Judge

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